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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,184	02/27/2002	Poonam Salotra	U 013891-8	8223

7590 08/20/2003  
LADAS & PARRY  
26 West 61 Street  
New York, NY 10023

EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

14

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/086,184

Applicant(s)

SALOTRA ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10 and 11 is/are rejected.
- 7) ☒ Claim(s) 5-9, 12 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's amendment filed September 25, 2002 in Paper No. 8 is acknowledged. However, the amendment to the specification was not entered because the margin at the top of the page was improper (See 37 CFR 1.52(a)(1) and 37 CFR 1.84(f)).

### ***Election/Restrictions***

2. Applicant's election without traverse of claims 1-4, 10, 11 and 13 in Paper No. 14 is acknowledged. However, an examination of claims 1-4, 10, 11 and 13 has indicated an allowable subject matter. Therefore, pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 5-9 and 12, directed to the process of using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 5-9 and 12 hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in Paper No. 14 is hereby withdrawn.

### ***Specification***

3. The disclosure is objected to because of the following informalities:

(a) The specification contains brackets at pages 2, 13 and 14 not intended to encompass an amendment (see 37 CFR 1.121 (e)(2)(ii)). It is suggested removing the brackets from the specification.

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(b) The specification is objected to because the designation of "SEQ ID Nos." or "SEQ ID No." or "SEQ ID NO." at pages 5-7 and 11 is improper. It is suggested changing "SEQ ID Nos." or "SEQ ID No." or "SEQ ID NO." to --SEQ ID NO:--(See MPEP 2422).

Appropriate correction is required.

### ***Claim Objections***

4. Claims 1, 3, 4, 5, 10, 11 and 13 are objected to because the following:

(a) Claims 1, 3, 4, 5, 10, 11 and 13 are objected to because the designation of "SEQ ID Nos." or "SEQ ID No." is improper. It is suggested changing "SEQ ID Nos." or "SEQ ID No." to --SEQ ID NO:--.

(b) Claims 3 and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims 3 and 4 are drawn to a PCR primer set as claimed in claim 1 wherein SEQ ID NO: 1 is 5'-AAATCGGCTCCGAGGCGGGAAAC-3' and SEQ ID NO: 2 is 5-GGTACACTCTATCAGTAGCAC-3'. The claims 3 and 4 do not further limit claim 1 because claim 1 recites "a first pair of oligonucleotides comprising the sequence given by SEQ ID NO: 1 and SEQ ID NO: 2". Therefore, the claimed limitations of claims 3 and 4 include every limitation of the parent claim.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-4 are indefinite because the claims suggest that multiple pairs of oligonucleotides are encompassed in the PCR primer set whereas only a first pair of oligonucleotides is disclosed with no subsequent pair of oligonucleotides (e.g., second pair of oligonucleotide) being disclosed or acknowledged. Clarification is required.

(b) Claims 10 and 11 are indefinite because of redundant recitation. It is suggested deleting one of the duplicate claims.

***Allowable subject matter***

7. Claims 1-13 contain allowable subject matter because the prior art does not teach or suggest a primer set specific for *Leishmania donovani*, said primer set being a pair of oligonucleotides comprising the sequence given by SEQ ID NO: 1 and SEQ ID NO: 2, wherein the primer set is effective in a PCR assay for detecting the presence of *Leishmania donovani* infecting in samples derived from patients infected by Leishmaniasis. The prior art also does not teach a method of detecting the presence of *Leishmania donovani* in a sample from a patient suspected of leishmaniasis comprising the use of the PCR primer set consisting of SEQ ID NOS: 1 and 2 in a PCR reaction.

The closest prior art, Kingsman et al. (US 4,918,166, April 1990) teaches a sequence that is 66.1% identical to the sequence of SEQ ID NO: 1 (see SEQ ID NO: 4). Gaines et al (US

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6,,469,152 B2, filing date June 28, 2001) teaches a sequence that is 69.5% identical to the sequence of SEQ ID NO: 2 (see SEQ ID NO: 15). No motivation could be found in the prior art for the claimed invention. Accordingly, an obviousness-type rejection against the claimed invention could not be made.

*Conclusion*

8. Claims 1-4, 10 and 11 are rejected. Claims 5-9, 12, 13 are objected. The claims are free of the prior art and contain allowable subject matter for the reasons indicated above.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.



Cynthia B. Wilder, Ph.D.  
Examiner  
Art Unit 1637

cbw  
August 6, 2003